UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

September 17, 1999

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Note to the Reader:

The attached draft commentary of the Health and Ecological Effects Subcommittee (HEES) of the Advisory Council on Clean Air Compliance Analysis (Council) is undergoing internal review. In its present form, the Chair considers that it represents the consensus of the HEES, but will not be released in final form until Council review and approval. The Council will consider the draft report at its publicly announced conference call meeting October 1st. Once the Council approves the report, it can be transmitted to the EPA Administrator. The final report will be available on request.

This draft has been released for general information. The reader should remember that this is an unapproved working draft and that the document should not be used to represent official EPA or SAB views or advice. Draft documents at this stage of the process often undergo significant revisions before the final version is approved and published.

The SAB is not soliciting comments on the advice contained herein. However, the SAB will accept comments on the issues listed below. The SAB is not obligated to address any responses which it receives.

1. Are any statements or responses made in the draft unclear?

2. Are there any technical errors?

For further information or to respond to the questions above, please contact:

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Insert Date

EPA-SAB-Council-ADV-99-###

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

RE: The Clean Air Act Amendments (CAAA) Section 812 Prospective Study of Costs and Benefits (1999): Advisory by the Health and Ecological Effects Subcommittee on Initial Assessments of Health and Ecological Effects; Part 2

Dear Ms. Browner:

On June 28-29, 1999, the Health and Ecological Effects Subcommittee (HEES) of the Advisory Council on Clean Air Compliance Analysis (Council) met to provide advice on four charge questions relating to the health and ecological effects associated with implementation of the 1990 Clean Air Act Amendments (CAAA of 1990, Section 812, Public Law 101-549, November 15, 1990, 104 Stat. 2399) projected to the year 2010. This meeting supplemented the discussion the HEES held on April 20-21, 1999 on seven initial charge questions. The HEES provided advice on those initial charge questions in Part 1 of this Advisory.

Introduction

In Part 2 of this Advisory, the Subcommittee addresses three charge questions relating to major categories of effects discussed in the Prospective Study: (1)

Ecological and Welfare Effects; (2) Health and Ecological Effects of Hazardous Air Pollutants (HAPs); and (3) Health Effects of Criteria Air Pollutants. The HEES provides a response to the following charge questions for each: (1) Are the input data used for each component of the analysis sufficiently valid and reliable for the intended analytical purpose?; (2) Are the models, and the methodologies they employ, used for each component of the analysis sufficiently valid and reliable for the intended analytical purpose?; (3) If the answers to either of the two questions above is negative, what specific alternative assumptions, data or methodologies does the Council recommend the Agency consider using for the first prospective analysis?

The HEES also addresses a specific charge question concerning existence of a 15 year lag between changes in PM exposure and changes in associated adverse health effects.

Ecological and Welfare Effects

The Project team responded well to the HEES' previous recommendations to include discussions of indirect effects of air pollutants on ecosystems and the need to eventually adopt a systems approach for the ecological analyses. For example, the paragraph on page 6-7 of the draft report illustrates complex interactions associated with the effects of nitrogen deposition in a watershed, wherein what at first glance might be construed as positive effects of increased nitrogen loading on growth of individuals and populations can result in negative impacts on communities and the ecosystem by changing community composition and causing anoxia in water bodies. In general, the exposition of ecological concepts related to air pollution has improved considerably during this first Prospective Analysis. However, we still have major concerns that are presented below.

Charge Question No. 1: Input Data. The input data are appropriate with respect to the selection of models for the economic assessment. There are several concerns regarding the methodologies, which in turn have implications for the input data. These concerns need to be recognized and are discussed in the next section.

Charge Question No. 2: Models and Methodologies. The models and methodologies for cost/benefit assessment with respect to ecological (ecology *per se*) and welfare (timber, fisheries, and agriculture) effects have several notable shortcomings. The most important are the following:

1. Methodologies for valuation of only a very limited number of ecosystem services are represented, and the present inability to value changes in many ecosystem service flows means that the noncommercial service flows from ecosystems are not captured in the economic valuation. A result of the inability to value ecosystem service flows is the intrinsic value of ecosystems (e.g., biodiversity) as well as the service flows that underpin the sustainability of human well being (e.g., climate modification, water purification and recharge, air purification, waste processing) are omitted from the cost of air quality. The omission of ecosystem service flow evaluations needs to be rectified in the future. The omission of evaluation of these service flows in this Prospective Study results in a substantial undervaluation of the benefits associated with the service flows from ecosystems. In addition, such omission undermines the Agency's commitment and mandate to protect ecological systems.
2. The methodology for valuing effects of tropospheric ozone on forest timber harvests has some shortcomings that have been presented repeatedly in the HEES advisory process. It is recommended that the document state the methodology's assets and liabilities.
3. The remainder of the models and methodologies (e.g., acid deposition and fisheries, nitrogen loading in estuaries) are appropriate for this exercise.
4. As noted above (No. 1), there are a host of ecological endpoints whose valuation is not presented (e.g., genetic resources, climate modification, detoxification of wastes). In previous discussions, the recommendation was made that these service flows be listed and referenced to the literature (e.g., Daly, Costanza). This recommendation was not adopted in the most recent draft of the Prospective Study, and we ask that appropriate reference material be added to the current Prospective Study.

Charge Question No. 3: Recommendation of Alternative Assumptions, Data or Methodologies. Because of resource constraints (time and financial resources), it is not feasible to rectify all the deficiencies noted above with respect to the valuation of ecological service flows in the current report to Congress. However, excluding agricultural crops, ecological effects were relegated to only two sentences in the Executive Summary (out of a four-page summary), and this is too little in light of EPA's mandate. We recommend at least explaining in the Executive Summary why so many

potentially important ecological benefits were not calculated and/or monetized for the current report. Moreover, we strongly recommend that the Agency re-commit to quantify and monetize ecological benefits in future efforts. A more balanced perspective on the benefits/costs with respect to ecological effects must be an area of emphasis in the next Prospective Study.

As noted above, the methodology for assessing commercial timber has some shortcomings. It is recommended that the document clearly articulate the assets as well as the liabilities of the methods used.

Finally, agricultural effects and other welfare effects should be combined in the chapter on ecological effects and be identified through an expanded title for the chapter.

Health and Ecological Effects of Hazardous Air Pollutants (HAPs)

Charge Question No. 1: Input Data. With respect to human health, the first Prospective Study has not quantitatively addressed toxic air contaminants. The HEES' recommends a workshop to develop the parameters for future evaluations of HAPs as a way to bring the necessary expertise to bear on this problem. The EPA plan for HAPs valuation proposed for the workshop at the June 28-29, 1999 meeting did not include defined goals for evaluation of the population exposure to HAPs. Instead, it was focused on the assessment of hazards. The HEES consensus is that a workshop solely to address hazard assessment issues will not meet the needs for future studies.

The HEES strongly recommends that the current plan for a workshop, as presented at the June 28-29, 1999 briefing, be expanded to provide a stronger focus on the exposure issues and on selecting the critical agents and mixtures that might be evaluated at the workshop and in the next prospective study. If necessary there could be more than one workshop planned, with the second workshop dealing with exposure-response issues for the selected HAPs. The HEES also advises that the initial workshop attempt to address methodological issues common to assessment of both health and ecological effects (see discussion of ecological issues at the end of the section of this Advisory addressing HAPs).

Charge Question No. 2: Models and Methodologies. The first Prospective Study does not quantitatively evaluate HAPs. Regarding exposure assessment, the EPA plans to couple the ASPEN (Assessment System for Population Exposure Nationwide)

and HAPEM (Hazardous Air Pollutant Exposure Model) models in order to generate preliminary national-scale exposure estimates for "certain" HAPs. The HEES suggests that there be a greater emphasis on evaluating the available and proposed environmental measurements and the use of these data to validate proposed air quality models. The predictive capability of ASPEN was questioned at an earlier HEES meeting and validation is still needed if this model is to be employed in subsequent 812 analyses. HEES recommends that EPA work with the Air Quality Modeling Subcommittee (AQMS) of the Council to examine a variety of air exposure models in order to select those that can accurately predict HAP exposures.

HEES is also concerned about the utility of the unit risk factors for generating best estimates for population impacts. The previous recommendation that EPA choose and evaluate case studies of a few selected HAPs should be implemented. This effort may provide insight into this issue.

Charge Question No. 3: Recommendation of Alternative Assumptions, Data or Methodologies. The Prospective Study refers to EPA's 1990 cancer risk study that indicated that as many as 1,000 to 3,000 cancers annually may be attributable to about a dozen well-studied HAPs compounds. It would be useful to indicate in the document which pollutants were judged important in that study. For example, a summary of the risk study could be presented as a matrix showing pollutant vs. health outcome.

Additionally, the potential benefits of reduced exposures to persistent contaminants (e.g. mercury) that might accrue from particulate matter (PM) reductions relevant to the 1990 CAAA should be mentioned, and a quantitative assessment of important toxins should be considered for the next Prospective Study.

Research needs can be divided into four parts: source assessment, exposure assessment, hazard assessment, and ecological assessment. HEES recommends that the exposure assessment begin with actual measurements of atmospheric concentrations in critical locations near sources and populations. HEES recognizes that, as part of the 812 process, exposure models are also required for future projections. However, these models need to be validated by comparison with atmospheric measurements in order to support both the initial selection of relevant HAPs and their subsequent exposure assessment.

The measurement activities need to determine: 1) which HAPs to monitor in urban air in order to establish a nationwide data base; and 2) which HAPs to use as

example case studies for 812 analysis. The first task is a challenging one, given that there are nearly 200 regulated compounds. However, it is an essential first step. Even in the absence of comprehensive air exposure models, these measurements would allow EPA to assess the magnitude and importance of atmospheric exposures for a given compound. This would then allow models to be tailored to those compounds of ultimate interest, with the assurance that their inhalation exposure route is worth describing in detail.

HEES recommends that the list of HAPs to be monitored be formulated using several different approaches. One practical approach is to consider those compounds that are planned to be measured by the national ambient monitoring network for air toxics being designed by EPA. This approach, however, begs the question of whether or not these particular compounds produce significant health effects at ambient concentrations.

As a parallel effort in the advancement of HAP exposure assessment, appropriate air quality models need to be developed for HAPs. These models should span a range of spatial scales, including not only local scales (point source impacts), but also urban (10-50 kilometer), meso (20-200 kilometers), and synoptic (100-1000 kilometers) scales. The models also need to include atmospheric chemistry and deposition processes. To this end, HEES recommends that EPA work with the AQMS to develop appropriate guidelines for selection and validation of models for this task. The Subcommittee also concurs with the AQMS recommendation that EPA continue to pursue the Models 3 framework.

In order to combine exposure and hazard assessments, HEES continues to recommend the development of several specific case studies. These case studies would use compounds for which there is an atmospheric measurement data base, and would attempt to cover the complete range of 812 analyses. The HEES previously recommended, and still recommends, that selected agents (benzene was suggested for human health effects, mercury and dioxins for ecological effects) be evaluated for the current Prospective Study. The HEES had not previously detailed the elements of that evaluation. As a suggestion, the evaluation should include an appraisal of the existing health effects literature, an inventory of data sources, an estimate of potential exposure and if insufficient information is available to perform an economic assessment then some idea of the scope of the potential problem could be indicated. This could

include numbers of people exposed and locations of possible high concentration "hot spots." This latter exercise would include a few key HAPs and would serve as a focal point for workshop discussions. From this initial evaluation it should be possible to identify data gaps and an identification of the types of resources that would be needed to fill those data gaps.

Although specific details of methods needed to evaluate the effects of HAPs on human health will differ from those needed for ecological effects, the general approach for human-health effects should not differ from the general approach for ecological effects. Overall, this approach probably will involve a three-step process requiring three mathematical functions: 1) emissions, meteorology, and atmospheric chemistry will be simulated in a comprehensive air quality model that is combined with ambient measurements to predict exposure concentrations, 2) the exposure concentration will be used to predict a biological response (e.g., changes in human health; changes in survival, growth, or reproduction of animals or plants; changes in nutrient cycling or other systems-level service flow), and 3) the biological response will be used to predict damages. The difference in damages between two model scenarios will be the estimated benefit associated with changing from one scenario to the other. Thus, any HAP could in concept be carried through the same general set of calculations for humans, wildlife, plants, ecosystems, etc., with only the details of how the models are generated differing among the target systems. It would be productive for the initial HAPs workshop to establish this overall analytical framework based on cross-fertilization between human-health specialists and ecologists, before diving into the details of human-health effects analyses.

But in reality, our knowledge of these three mathematical functions for any receptor is limited and will not be improved until specific research is conducted to address several shortcomings. Thus, at present, the Agency might need to *a priori* classify each of the HAPs into one or more of six groups of a two-factor matrix, in which two categories of uniformity of exposure across a region (homogeneous across a region versus heterogeneous [i.e., localized high concentrations surrounded by much lower concentrations]) are crossed with three categories of toxicity (toxic to humans versus toxic to non-humans versus adversely affecting ecosystem functions). The specifically tailored analytical procedures might differ considerably among HAPs. However, harmonizing the approaches as much as possible early in the procedure might help

prevent the appearance of disconnects between the human-health and ecological approaches later.

Health Effects of Criteria Air Pollutants.

Charge Question No. 1: Input Data. Much of the epidemiological data, particularly the PM-mortality data have not been validated for causality. Thus, there is an assumed relationship between mortality and PM at present ambient concentrations. Since the Agency has chosen to assume the relationships are valid and reliable, appropriate caveats are in order. We believe, based on oral advice given the Agency and commitments made by the Agency at our meeting on June 28-29, 1999 to modify specific text that is deficient or contradictory, that the Agency will put appropriate caveats in place.

Charge Question No. 2: Models and Methodologies. The Subcommittee believes that they are adequate for the purposes of the Prospective Study.

Charge Question No. 3: Recommendation of Alternative Assumptions, Data or Methodologies. The dominant role of premature mortality on the benefits calculations makes it especially important to support and/or encourage further prospective cohort mortality studies that consider multiple air pollutants as potential causal factors.

15-Year Lag for Particulate Matter Effects

Charge question: "It has been suggested to the Agency that the WHO (1996) study provides scientific evidence of the existence of a 15 year lag between changes in PM exposure and changes in associated adverse health effects. Heretofore, however, the Agency has interpreted the WHO authors' summing of incidences at the end of the 15 exposure period of the Dockery study as a matter of mathematical convenience, not evidence of the WHO authors' belief in the existence or magnitude of a lag between changes in exposure and changes in risk of adverse health effect. What is the SAB HEES view regarding the proper interpretation and use of the WHO (1996) study? Specifically, does the HEES believe it is reasonable to assume that, based on the WHO (1996) study or other evidence, there is no reduction in risk of adverse health consequences until 15 years following a reduction in PM exposure?"

Response: Contrary to the June 17, 1999 letter from Arbuckle and Blank to Donald Barnes, there are no statements in the 1996 WHO report to suggest that there is any scientific evidence for the existence of a 15 year lag between changes in PM exposure

and mortality. On page 35 of the WHO report (last paragraph, third line from bottom), the authors state that "for simplification [emphasis added], it was assumed that the effect of particulate matter only started to become manifest after 15 years in subjects who were 27.5 [years of age] initially . . . " No citations from the published literature are given to support the 15-year lag assumption, nor is the issue further discussed within the WHO report. Thus it is clear that the authors of the WHO report used a 15-year lag assumption strictly "for simplification," which can be interpreted as a convenient statistical device for estimating the mortality effects from chronic exposure of the population to particulate air pollution.

There is considerable evidence, cited in both the WHO report and EPA's 1995 Air Quality Criteria Document for Particulate Matter, that daily variations in PM have an immediate effect on mortality risk within a one to five day interval between elevated PM concentrations and excess mortality. This effect was particularly apparent for cardiovascular and respiratory causes of death among the elderly. These observations are commonly interpreted as implying that the acute mortality effect of PM occurs among a particularly susceptible segment of the population whose health status is already compromised by pre-existing disease. Thus with a reduction in PM levels, it is reasonable to expect that there will be some immediate benefits from mortality reductions among susceptible individuals.

However, the magnitude of estimated mortality effects from the cohort studies of Dockery et al. (1993) and Pope et al. (1995) are different than the estimates from the time-series studies. The WHO report estimates a 10% mortality increase per 10µg/m^3 annual difference in PM from the cohort studies, whereas the time-series studies show an overall 1-2% mortality increase per 10µg/m^3 daily variation in PM. The different estimates from the cohort studies, even when they are adjusted for the differences in time duration, may be attributable to three consequences of PM exposures: (1) cumulative PM exposures of the entire population may result in a PM-induced increase in the number of individuals who become susceptible to the acute mortality effects observed in the time series studies; (2) cumulative PM exposure may cause chronic diseases which increase the mortality rate of the population, but the deaths of a portion of these chronically ill persons may occur independently of the daily variations in PM exposure, and these latter deaths are not captured by the time series studies; and (3) a

10µg/m^3 change in annual average concentration may be associated with a much larger change in peak 24-hour exposure levels.

Given that the mortality effect of cumulative air pollution exposure exceeds that of daily variations in exposure, the question becomes, over what time period does the excess effect manifest itself in the population? As noted above, some of the mortality effects of cumulative exposures will occur over short periods of time in individuals with compromised health status, but other effects are likely to occur among individuals who, at baseline, have reasonably good health that will deteriorate because of continued exposure. No animal models have yet been developed to quantify these cumulative effects, nor are there epidemiologic studies bearing on this question. As the HEES previously stated, "consideration of time lags on annual mortality outcomes might be premature" ("CAAA (1990) Section 812 Prospective Study Health & Ecological Effects Initial Studies," EPA-SAB-COUNCIL-ADV-99-005). Neither the 1996 WHO report nor do any recently published studies provide reasons to revise this statement.

Although there is substantial evidence that a portion of the mortality effect of PM is manifest within a short period of time, i.e., less than one year, it can be argued that, if no a lag assumption is made, the entire mortality excess observed in the cohort studies will be analyzed as immediate effects, and this will result in an overestimate of the health benefits of improved air quality. Thus some time lag is appropriate for distributing the cumulative mortality effect of PM in the population. The HEES concurs with the approach proposed by EPA at the June 29th meeting on this issue, and recommends that the Tier 2 SA Lag estimates as presented at the meeting (Table entitled "Sensitivity to Lag Assumption" Attached in Appendix A) be considered as the best estimate for use in the 1999 Section 812 report. HEES also recommends that a sensitivity analysis of the time lag issue should also be presented in the report. The sensitivity analysis should include a higher end and a lower end mortality estimate (e.g., 0, 8, 15-year lags), in which the higher end estimate would include a no-lag assumption, as given in the second column of the above table, and the lower end estimate would replicate the analysis used in the 1996 WHO report. The latter analysis has been published in the peer-reviewed literature (Brunekreef B., "Air pollution and life expectancy: is there a relation?" *Occupational Environmental Medicine,* 1997; 54:781-4). The Brunekreef analysis clearly results in an underestimate of the immediate mortality effect of PM, since, as discussed above, there is ample evidence for a short

term mortality effect of PM, but the 15-year lag analysis presented by Brunekreef provides a statistically simplified approach to estimating the potential delayed effect of PM exposures for a young and relatively healthy segment of the population.

Summary Statement on Research Needs

The HEES commends the Agency for its efforts in developing the first Prospective Study. In fact, it has been an enlightening exercise which demonstrates the deficiencies in data and models to adequately define exposure and health endpoints for human and ecological systems. Research needs for future Section 812 Studies need to be seriously considered by the Administrator and the Office of Research and Development. Targeted studies need to be developed and executed cooperatively by the Agency and researchers in the appropriate fields of ecology, exposure, and health effects.

Conclusion

We thank the Agency for the opportunity to be of service in review of the draft Prospective Study and to the review of the draft Study itself. We look forward to the response to this Advisory from the Assistant Administrators of the Office of Air and Radiation and the Office of Research and Development.

Sincerely,

Dr. Maureen L. Cropper, Chair	Dr. Paul Lioy, Chair
Advisory Council on Clean Air	Health and Environmental Effects
Compliance Analysis	Subcommittee